

§ 20.93

0.5-ounce sample of the essential oil used in the article. The appropriate TTB officer may also require the manufacturer to submit a sample of any ingredient which is not adequately described in the formula.

(b) For each formula submitted in accordance with § 20.91, the appropriate TTB officer may require the manufacturer to submit a 4-ounce sample of the finished article.

(c) The appropriate TTB officer may, at any time, require submission of samples of:

(1) Any ingredient used in the manufacture of an article, or;

(2) Any article.

[T.D. ATF- 199, 50 FR 1962, Mar. 6, 1985, as amended by T.D. ATF-435, 66 FR 5474, Jan. 19, 2001]

§ 20.93 Changes to formulas.

(a) *General.* Except as provided in paragraph (b) of this section, any change of ingredients or quantities of ingredients listed in an approved formula shall constitute a different article for which a different approved formula is required by § 20.91.

(b) *Exceptions.* A different approved formula is not required for the following—

(1) A change from an ingredient identified in the formula by a brand name to the same quantity of a chemically identical ingredient acquired under a different brand name, or

(2) A change of an ingredient which is a coloring material.

§ 20.94 Statement of process.

(a) Manufacturers shall submit a statement of process on Form 5150.19, in accordance with paragraph (b) of this section, covering the following activities:

(1) If specially denatured spirits are used for laboratory or mechanical purposes, other than use of S.D.A. Formula No. 3-A, 3-C, or 30 for laboratory or mechanical purposes not in the development of a product;

(2) If specially denatured spirits are used in a manufacturing process in which none of the specially denatured spirits remains in the finished product;

(3) If specially denatured spirits, completely denatured alcohol, or arti-

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cles are used in a manufacturing process and are to be recovered; or

(4) If recovered denatured spirits are to be redenatured.

(b) The manufacturer shall submit a separate Form 5150.19 for each activity described in paragraph (a) of this section describing the process completely.

(1) If specially denatured spirits are used for laboratory or mechanical purposes, other than use of S.D.A. Formula No. 3-A, 3-C, or 30 for laboratory or mechanical purposes not in the development of a product, the Form 5150.19 shall identify the formula number of specially denatured spirits, a description of the laboratory or mechanical use, and the approximate annual quantity to be used.

(2) If the Form 5150.19 is submitted covering activities described in paragraphs (a)(2), (a)(3), or (a)(4) of this section, the Form 5150.19 shall also contain the following information:

(i) Flow diagrams shall be submitted with the Form 5150.19 clearly depicting the equipment in its relative operating sequence, with essential connecting pipelines and valves. All major equipment shall be identified as to its use. The direction of flow through the pipelines shall be indicated in the flow diagram. The flow diagram, shall be accompanied by a written description of the flow of materials through the system.

(ii) The statement of process shall describe the chemical composition of the recovered spirits. The statement of process shall be accompanied by a statement of the intended use of the recovered spirits.

§ 20.95 Developmental samples of articles.

(a) A user may use limited quantities of specially denatured spirits in the manufacture of samples of articles for submission in accordance with § 20.92.

(b) A user may prepare developmental samples of articles, of limited sizes and quantities, for one-time shipment to prospective customers. The user shall maintain records showing—

(1) The types of product samples prepared,

(2) The size and number of samples sent, on a one-time basis, to each prospective customer, and